Accuracy and Repeatability of a New Portable Ultrasound Pachymeter

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ABSTRACT

Purpose: To assess the accuracy and repeatability of central corneal thickness measurements taken with a new portable ultrasound pachymeter.

Methods: Central thickness measurements were taken with a portable and a conventional ultrasound pachymeters in 57 right corneas of fifty-seven young adults (19 males, 38 females) aged 18 to 44 years (mean ± SD, 22.95 ± 3.92). Three repeated measures were obtained and then compared to obtain the repeatability of each instrument and the agreement between both pachymeters. The three readings taken with the portable pachymeter were compared against each other in order to evaluate intra-session repeatability and bias of each individual measurement regarding the mean of three.

Results: Mean values of central corneal thickness were 537±35 μm for conventional and 534±35 μm for the new portable pachymeter. A high agreement was found between the two instruments (mean difference=2.58μm; 95%CI 1.41 to 3.75 μm) with only 2 eyes presenting differences larger than ±8.6μm (95% CI) which represents 1.6% of the mean corneal central corneal thickness. The first reading take showed the higher agreement with the mean value for the portable pachymeter.

Conclusions: The instrument tested in this study is able to take reliable measurements of corneal thickness even if a single reading is considered. Intra-session repeatability was very high as it was also the agreement between the average of three readings taken with the two ultrasound pachymeters.

Key-words: corneal thickness, pachymeter comparison, portable ultrasound pachymetry.

INTRODUCTION

Corneal thickness (CT), as measured by pachymetry, is a sensitive indicator of corneal health and physiological performance.

Despite the numerous new pachymetric techniques available, ultrasound (US) technology is one of the most commonly accepted in terms of accuracy, being the gold standard against most of the new devices are being tested.(Bovelle *et al.* 1999; Gonzalez-Meijome *et al.* 2003; Iskander *et al.* 2001;Lackner *et al.* 2005;Marsich and Bullimore 2000;Modis, Jr. *et al.* 2001;Wirbelauer *et al.* 2002;Wirbelauer *et al.* 2004) A recent investigation involving two US pachymeters, confocal microscopy and slit scanning pachymetry, concluded that both US pachymeters gave the most consistent measurements of corneal thickness with standard deviations of the difference between two consecutive measurements as small as 6 μm and 7 μm.(McLaren *et al.* 2004)

Despite the need of contact with the cornea, ultrasound pachymetry is still at the forefront of the techniques used to obtain rapid, accurate and reproducible measurements of corneal thickness at a reasonable cost, when compared with most of the modern devices quoted above. Portability of clinical instruments allows to optimize their use even in situations out of the clinical environment, making them excellent tools for screening and field data acquisition.

In the present study we aim to validate a new portable US pachymeter for the measurement of central corneal thickness (CCC). This is an important issue because of its potential usefulness in clinical practice due to its relatively reduced cost and portability.

MATERIAL AND METHODS

Fifty-seven right eyes from 57 patients (19 males, 38 females), with ages ranging from 18 to 44 years (mean ± SD, 22.95 ± 3.92 years), were selected to participate in this study. Inclusion criteria required that the subjects did not suffer from any ocular condition or injury, except for ocular hypertension or glaucoma, at the moment of the study. Slit-lamp examination and interview were carried out prior data acquisition in order to ensure that none of the subjects exhibited corneal disease or corneal scarring, had been previously submitted to corneal refractive surgery, nor were taking any ocular or systemic medication. The research followed the tenets of the Declaration of Helsinki and was reviewed and approved by the Scientific Committee of the School of Sciences of Minho University (Portugal).

After explaining the nature of the experimental procedures, informed consent was obtained from each subject prior to data acquisition. Corneal thickness was measured with a conventional ultrasound biometer/pachymeter, the Nidek UP-1000 (Nidek Technologies, Gamagori, Japan) and a new portable pachymeter, the SP 100 Handy pachymeter (Tomey, Nagoya, Japan). This new portable pachymeter operates at 20 MHz measuring thicknesses in the range from 150 to 1200 μm at calibration speeds ranging from 1400 to 2000 m/s.

One drop of 1% tetracaine hydrochloride was instilled before pachymetric readings were taken by a trained clinician avoiding excessive compression of the tip probe against the cornea. Both pachymeters were calibrated prior data acquisition at each measurement session. Calibration was accepted when five measurements of the test block were taken with an accuracy of ± 1μm before start each measurement session. Ultrasound speed was set at 1640 m/s for a vibration frequency of 20 MHz in both instruments according to the most commonly used in experiments involving human corneas and the recommended by most of the manufacturers.

In order to avoid the potential effect of epithelial compression on consecutive measurements at the same location, both instruments were randomly applied. To ensure the repeatability of the positioning of the pachymeter in subsequent measurements, a fixation panel was placed in front of the patient so that the tip probe contacted the cornea at the visual center. This system has been previously used successfully to obtain reproducible central and peripheral corneal thickness measurements with ultrasound pachymetry.(Gonzalez-Meijome *et al.* 2003;Parafita *et al.* 1999;Parafita *et al.* 2000) Three repeated measurements were taken consecutively with each instrument and averaged for subsequent comparisons.

As CT measurements taken by US pachymetry could be adversely affected by fluctuations in tissue hydration related to US speed through the cornea, contact lens users were excluded from the study. All measurements were recorded in the afternoon, between 16:00 and 20:00h, considered as the most stable part of the day for thickness fluctuations and, in such period, US speed through the cornea could meet with the calibration settings of the US probe.(Du *et al.* 2003)

Data were analyzed using the statistical package SPSS version 14.0. Correlations between central and peripheral measurements were assessed statistically as the mean of the differences compared with zero. The 95% limits of agreement (LoA = mean of the difference ± 1.96 x S.D. of the differences) were also calculated.(Bland and Altman 1986) After normality and equality of variances was assessed, parametric tests were performed to assess the bias between instruments. The hypothesis of zero bias was examined by Student t-test. The level of significance was established at $\alpha=0.05$.

RESULTS

Mean central corneal thickness (CCT) was 537±35 μm for the Nidek UP-1000 and 534±35 μm for the Tomey SP-100 handy pachymeter. The mean difference between both instruments was 2.58±4.39 μm which was statistically different from zero ($t = 4.44$; $p<0.001$; Paired T-test). However this is a value not likely to have any clinical significance. Plots of difference between both instruments are presented in figure 1, displaying a high agreement between both instruments with only 2 eyes beyond 95% limits of agreement. There is a slight trend towards underestimation of higher CCT and overestimate of lower CCT by the portable Tomey SP-100 when compared with Nidek UP-1000. However this trend was not statistically significant ($r=0.124$; $p=0.359$). According to these data, we can ensure that CCT with the Tomey SP-100 Handy Pachymeter can be obtained with a mean difference of 2.58±8.61 μm when compared to a conventional (non-portable) pachymeter.

Table 1 presents mean value, standard deviation, maximum and minimum values within each one of the three readings taken with Tomey SP-100 Handy Pachymeter used to compute the mean value that was compared to Nidek UP-1000 described above. All the three measurements follow a strong correlation among themselves ($r>0.99$; $p<0.001$). Only differences between the first and the third measurement were statistically different from zero ($t=-3.34$; $p=0.001$). However the mean difference of -1.42±3.21 μm doest not have any clinical relevance. Conversely, the stronger correlation ($r=0.996$; $p<0.001$) and the least mean difference (-0.63±3.94 μm) was found between second and third measurements ($t=-1.21$; $p=0.232$).

Comparing each single reading taken with Tomey SP-100 against the mean of three readings we found a closer agreement between average value and the first reading (mean difference±SD = 0.28±1.38μm) followed by second one (0.67±1.56μm) and third one (0.99±1.54μm).

DISCUSSION

It is well known the importance of CT in many clinical situations, such as diagnosis of corneal ectatic conditions, corneal physiology, contact lens research or refractive surgery procedures. There are several optical methods to estimate the corneal thickness, and a wide body of related literature is available regarding this subject.(Parafita *et al.* 2002) Conversely, US pachymetry has been a standard for the estimation of CT for the last decades, and now that modern optically based pachymetric techniques are commercially available, US pachymetry is the reference for testing all of them.(Bovelle *et al.* 1999; Gonzalez-Meijome *et al.* 2003;Iskander *et al.* 2001;Lackner *et al.* 2005;Marsich and Bullimore 2000;Modis, Jr. *et al.* 2001;Wirbelauer *et al.* 2002;Wirbelauer *et al.* 2004)

Mean values and standard deviations found in the present study for the CCT of young healthy humans agree with most of the accepted values of CCT referred in the literature US pachymetry in normal corneas.(Bovelle *et al.* 1999;Doughty *et al.* 2002; Gonzalez-Meijome *et al.* 2003;Lackner *et al.* 2005;Marsich and Bullimore 2000;Yaylali *et al.* 1997)

If we can assume a bias of ±4 μm, one measurement will be enough with this instrument. These values are in the same order or magnitude and even slightly lower than those reported by other authors for two consecutive measurements with US pachymetry (Bovelle *et al.* 1999;McLaren *et al.* 2004) and supports the precision in pachymeter position among the repeated measurements. Gillis *et al*. reported similar values for 5 repeated measurements with US pachymetry.(Gillis and Zeyen 2004) Nevertheless, despite the first single reading has demonstrated the higher level of agreement with the average of three, the authors recommend to take 3 repeated measurements to ensure accuracy. Moreover, in such a situation, the last two readings demonstrated the highest intra-session agreement in the present study.

For the majority of the clinical applications, including refractive surgery, corneal health screening, contact lens effects on the corneal physiology, or correction of intraocular pressure measurements, the new portable SP-100 US Pachymeter report reliable measurements.

Obviously, when comparing instruments, the different principles in what they are based are important handicaps to find agreement. This is the case of pachymetry when comparing US and optical methods, and all the new devices available in the marketplace are based on optical principles. Modified optical pachymetry has also shown a high degree of repeatability in measuring both total and epithelial thickness.(Alharbi *et al.* 2005;Alharbi and Swarbrick 2003;Perez *et al.* 2003) However its limited availability does not allow taking it as "gold standard" for most clinicians and investigators. So, we suggest that future comparisons among central and peripheral corneal thickness measurements with different devices will include US pachymetry as it is, in the hands of an experienced observer, the most reliable method for corneal thickness measurement.

In summary, the present study has evidenced the accuracy and repeatability of a new portable US pachymeter for the measurement of CCT in healthy human corneas. Portable instruments have several advantages for clinical and research applications. The lower cost of these units is also a matter of fact.

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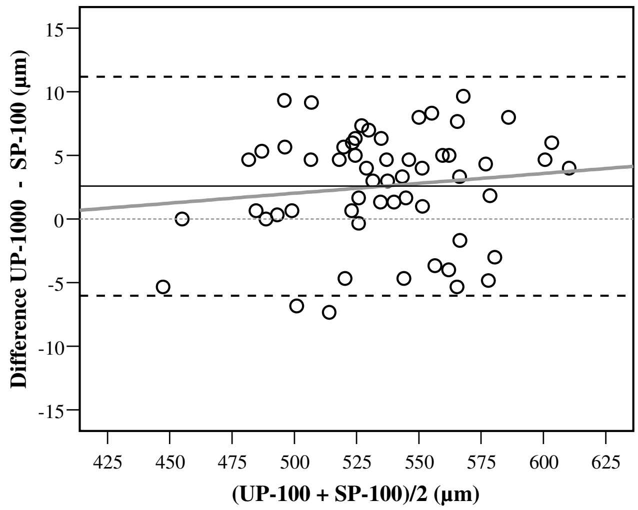
The authors wish to thank ISAZA for the loan of the Tomey SP-100 Handy Pachymeter. None of the authors has a commercial or financial interest in the instruments presented here.

Table 1. Descriptive statistics of the three measurements taken within the same session at corneal center with Tomey SP-100. Units are microns (μm)

		Minimum	Maximum	Mean	Standard Deviation
Tomey SP-100	**1st reading**	451	606	533	34
	2nd reading	450	610	534	34
	3rd reading	449	609	535	34
	Mean	450	608	534	34
Nidek UP-1000	**Mean**	445	612	537	35

Figure 1. Plot of difference against mean CCT values obtained with the two pachymeters (r=0.124; p=0.359)



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